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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,417	01/04/2002	Ramesh Kekuda	21402-235 (CURA-535)	7162

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EXAMINER	
MARTINELL, JAMES	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,417	KEKUDA ET AL.	
	Examiner	Art Unit	
	James Martinell	1631	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 38, and 41, drawn to polypeptides, pharmaceutical compositions, and kits, classified in class 530, subclass 350.

II. Claims 5-14, 19-21, 39, 42, 46, and 47, drawn to nucleic acids, vectors, host cells, nucleic acid hybridization assays, pharmaceutical compositions, and kits, classified in class 536, subclasses 23.5 and 23.1, and class 435, subclasses 6, 320.1, 325, and 252.3.

III. Claims 15-18, 40, and 43, drawn to antibodies, antibody assays, pharmaceutical compositions, and kits, classified in class 530, subclass 387.1 and class 435, subclass 7.1.

IV. Claims 22, and 23, drawn to methods for identifying protein binding agents, classified in class 435, subclass 7.1.

V. Claim 24, drawn to methods for identifying agents that modulate expression or activity of polypeptides, classified in class 435, subclass 4.

VI. Claim 25, drawn to methods of treatment using compounds of undisclosed nature, classified in class unknown, subclass unknown.

VII. Claims 26-29 and 48, drawn to methods of treatment using polypeptides, classified in class 514, subclass 12.

VIII. Claims 30-33, drawn to methods of treatment using nucleic acids, classified in class 514, subclass 44.

IX. Claims 34-37 and 49, drawn to methods of treatment using antibodies, classified in class 530, subclass 387.1.

X. Claims 44 and 45, drawn to methods of diagnosis by protein measurement, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other for the following reasons. The polypeptides, pharmaceutical compositions, and kits of Group I are materially different from and are therefore independent and distinct from the nucleic acids, vectors, host cells, pharmaceutical compositions, and kits of Group II, and the antibodies, pharmaceutical compositions, and kits of Group III. The

polypeptides, pharmaceutical compositions, and kits of Group I are not needed to practice the assays of Groups II or III or the methods of Groups V, VI, VIII, IX, or X. The polypeptides, compositions, and kits of Group I have uses other than in the methods of Groups IV or VII (*e.g.*, in affinity chromatography). The nucleic acids, vectors, host cells, pharmaceutical compositions, and kits of Group II are materially different from and are therefore independent and distinct from the antibodies, pharmaceutical compositions, and kits of Group III. The nucleic acids, vectors, host cells, pharmaceutical compositions, and kits of Group II are not needed to practice the methods of any of Groups III-VII, IX, or X. The methods of each of Groups II-X may each be practiced independently of one another. The nucleic acids, vectors, host cells, pharmaceutical compositions, and kits of Group II have uses other than the methods of Group VIII (*e.g.*, in affinity chromatography). The antibodies of Group III are not needed to practice the methods of any of Groups IV-VIII and X. The antibodies of Group III have uses other than the methods of Group IX (*e.g.*, in affinity chromatography).

Claims 5-14, 19-21, 30-33, 39, 42, 46, and 47 are drawn to nucleotides, nucleotide constructs, and/or methods requiring the use of nucleotides or nucleotide constructs that contain more than one individual, independent, and distinct nucleotide sequence in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (November 19, 1996). This notice permits the examination of from one to ten independent and distinct nucleotide sequences in a single application based upon USPTO resources.

Should applicant elect a Group that claims or mentions more than one polynucleotide sequence, applicant is further required to select no more than ONE of the individual sequences for examination. The search of the no more than ONE selected sequence may include the complement of the selected sequence and, where appropriate, may include e subsequences within the selected sequence (*e.g.,* oligomeric probes and/or primers).

Claims 1-4, 15-18, 22-29, 34-38, 40, 41, 43-45, and 48 are drawn to large numbers of polypeptides or mention or require the use of large numbers of polypeptides. Should applicant elect a

Group that claims or mentions more than one polypeptide sequence, applicant is further required to elect one polypeptide sequence within the elected Group for examination on the merits.

To search any two groups as outlined above would create an undue burden for the U.S. PTO because the searches of the non-patent literature are not only non-overlapping to any appreciable extent, but are also divergent in nature.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Reminder Regarding *In re Ochiai* and *In re Brouwer*

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner bee the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028.

PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

James Martinell, Ph.D.
Primary Examiner
Art Unit 1631